

**§ 862.1560 Urinary phenylketones (nonquantitative) test system.**

(a) *Identification.* A urinary phenylketones (nonquantitative) test system is a device intended to identify phenylketones (such as phenylpyruvic acid) in urine. The identification of urinary phenylketones is used in the diagnosis and treatment of congenital phenylketonuria which, if untreated, may cause mental retardation.

(b) *Classification.* Class I.

**§ 862.1565 6-Phosphogluconate dehydrogenase test system.**

(a) *Identification.* A 6-phosphogluconate dehydrogenase test system is a device intended to measure the activity of the enzyme 6-phosphogluconate dehydrogenase (6 PGD) in serum and erythrocytes. Measurements of 6-phosphogluconate dehydrogenase are used in the diagnosis and treatment of certain liver diseases (such as hepatitis) and anemias.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807.

[52 FR 16122, May 1, 1987, as amended at 53 FR 21449, June 8, 1988]

**§ 862.1570 Phosphohexose isomerase test system.**

(a) *Identification.* A phosphohexose isomerase test system is a device intended to measure the activity of the enzyme phosphohexose isomerase in serum. Measurements of phosphohexose isomerase are used in the diagnosis and treatment of muscle diseases such as muscular dystrophy, liver diseases such as hepatitis or cirrhosis, and metastatic carcinoma.

(b) *Classification.* Class I.

**§ 862.1575 Phospholipid test system.**

(a) *Identification.* A phospholipid test system is a device intended to measure phospholipids in serum and plasma. Measurements of phospholipids are used in the diagnosis and treatment of disorders involving lipid (fat) metabolism.

(b) *Classification.* Class I. The device is exempt from the premarket notification

procedures in subpart E of part 807.

[52 FR 16122, May 1, 1987, as amended at 53 FR 21449, June 8, 1988]

**§ 862.1580 Phosphorus (inorganic) test system.**

(a) *Identification.* A phosphorus (inorganic) test system is a device intended to measure inorganic phosphorus in serum, plasma, and urine. Measurements of phosphorus (inorganic) are used in the diagnosis and treatment of various disorders, including parathyroid gland and kidney diseases, and vitamin D imbalance.

(b) *Classification.* Class I.

**§ 862.1585 Human placental lactogen test system.**

(a) *Identification.* A human placental lactogen test system is a device intended to measure the hormone human placental lactogen (HPL), (also known as human chorionic somatomammotrophin (HCS)), in maternal serum and maternal plasma. Measurements of human placental lactogen are used in the diagnosis and clinical management of high-risk pregnancies involving fetal distress associated with placental insufficiency. Measurements of HPL are also used in pregnancies complicated by hypertension, proteinuria, edema, post-maturity, placental insufficiency, or possible miscarriage.

(b) *Classification.* Class II.

**§ 862.1590 Porphobilinogen test system.**

(a) *Identification.* A porphobilinogen test system is a device intended to measure porphobilinogen (one of the derivatives of hemoglobin which can make the urine a red color) in urine. Measurements obtained by this device are used in the diagnosis and treatment of porphyrias (primarily inherited diseases associated with disturbed porphyrine metabolism), lead poisoning, and other diseases characterized by alterations in the heme pathway.

(b) *Classification.* Class I.

**§ 862.1595 Porphyrins test system.**

(a) *Identification.* A porphyrins test system is a device intended to measure porphyrins (compounds formed during

the biosynthesis of heme, a constituent of hemoglobin, and related compounds) in urine and feces. Measurements obtained by this device are used in the diagnosis and treatment of lead poisoning, porphyrias (primarily inherited diseases associated with disturbed porphyrin metabolism), and other diseases characterized by alterations in the heme pathway.

(b) *Classification.* Class I.

**§ 862.1600 Potassium test system.**

(a) *Identification.* A potassium test system is a device intended to measure potassium in serum, plasma, and urine. Measurements obtained by this device are used to monitor electrolyte balance in the diagnosis and treatment of diseases conditions characterized by low or high blood potassium levels.

(b) *Classification.* Class II.

**§ 862.1605 Pregnanediol test system.**

(a) *Identification.* A pregnanediol test system is a device intended to measure pregnanediol (a major urinary metabolic product of progesterone) in urine. Measurements obtained by this device are used in the diagnosis and treatment of disorders of the ovaries or placenta.

(b) *Classification.* Class I.

**§ 862.1610 Pregnanetriol test system.**

(a) *Identification.* A pregnanetriol test system is a device intended to measure pregnanetriol (a precursor in the biosynthesis of the adrenal hormone cortisol) in urine. Measurements obtained by this device are used in the diagnosis and treatment of congenital adrenal hyperplasia (congenital enlargement of the adrenal gland).

(b) *Classification.* Class I.

**§ 862.1615 Pregnenolone test system.**

(a) *Identification.* A pregnenolone test system is a device intended to measure pregnenolone (a precursor in the biosynthesis of the adrenal hormone cortisol and adrenal androgen) in serum and plasma. Measurements obtained by this device are used in the diagnosis and treatment of diseases of the adrenal cortex or the gonads.

(b) *Classification.* Class I.

**§ 862.1620 Progesterone test system.**

(a) *Identification.* A progesterone test system is a device intended to measure progesterone (a female hormone) in serum and plasma. Measurements obtained by this device are used in the diagnosis and treatment of disorders of the ovaries or placenta.

(b) *Classification.* Class I.

**§ 862.1625 Prolactin (lactogen) test system.**

(a) *Identification.* A prolactin (lactogen) test system is a device intended to measure the anterior pituitary polypeptide hormone prolactin in serum and plasma. Measurements obtained by this device are used in the diagnosis and treatment of disorders of the anterior pituitary gland or of the hypothalamus portion of the brain.

(b) *Classification.* Class I.

**§ 862.1630 Protein (fractionation) test system.**

(a) *Identification.* A protein (fractionation) test system is a device intended to measure protein fractions in blood, urine, cerebrospinal fluid, and other body fluids. Protein fractionations are used as a aid in recognizing abnormal proteins in body fluids and genetic variants of proteins produced in diseases with tissue destruction.

(b) *Classification.* Class I.

**§ 862.1635 Total protein test system.**

(a) *Identification.* A total protein test system is a device intended to measure total protein(s) in serum or plasma. Measurements obtained by this device are used in the diagnosis and treatment of a variety of diseases involving the liver, kidney, or bone marrow as well as other metabolic or nutritional disorders.

(b) *Classification.* Class II.

**§ 862.1640 Protein-bound iodine test system.**

(a) *Identification.* A protein-bound iodine test system is a device intended to measure protein-bound iodine in serum. Measurements of protein-bound iodine obtained by this device are used in the diagnosis and treatment of thyroid disorders.